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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,532	02/09/2001	Clive Wood	GNN-012CP	8383
<div>Ivor R. Elrifi MINTZ LEVIN COHEN COHN FERRIS GLOVSKY AND POPEO PC One Financial Center Boston, MA 02111</div>			<div>EXAMINER QIAN, CELINE X</div>	
			<div>ART UNIT 1636</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 05/03/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/780,532	WOOD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celine X. Qian Ph.D.	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3,5-8,39-43 and 45-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-8,39-43 and 45-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Claims 2, 3, 5-8, 39-43, 45-68 are pending in the application.

This Office Action is in response to the Amendment filed on 9/28/06.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/28/06 has been entered.

#### ***Response to Amendment***

The rejection of claims 2, 3, 5-8, 39-43, 45-68 under 35 U.S.C.112 1<sup>st</sup> paragraph is maintained for reasons set forth of the record mailed on and further discussed below.

Claims 2, 3, 5-8, 39-43, 45-52, 66 and 67 are rejected under 35 U.S.C.112 2<sup>nd</sup> paragraph for reasons set forth below.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 5-8, 39-43, 45-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection necessitated by Applicant's amendment.**

In the response filed on 9/28/06, Applicants assert that support for "cells with TRADE activity" is found on page 11, lines 1-13. A review of the instant specification reveals the teaching with regard to "TRADE activity" and over-expressing TRADE in a cell that results in activation of NFkB and JNK pathways. However, the cited section does not support for the instantly claimed method of modulating activation of an NFkB signaling pathway in a cell comprising contacting a cell having TRADE activity with a TRADE polypeptide, wherein the TRADE polypeptide comprises the extracellular domain of a TRADE $\alpha$  polypeptide, encoded by a polynucleotide at least 98% homologous to a polynucleotide encoding amino acids 1-168 of SEQ ID NO:2. The later disclosed example 11 teaches the deletion analysis of TRADE and NFkB activation signal in 293 T cells, however, it is unclear whether the 293 T cells comprises endogenous TRADE activity. As such, the amendment to the claims constitutes new matter. Applicants are invited to point to specific teaching in the instant specification that supports the current amendment to obviate this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 5-8, 39-43, 45-52, 66 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the recitation of "said extracellular domain corresponding to a polypeptide" renders the claim indefinite because it is unclear what sequences the extracellular

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domain has. In other words, does “corresponding” mean the extracellular having sequence homology with the polypeptide 98% homologous to SEQ ID NO:2, or the extracellular domain has same activity with the polypeptide 98% homologous to SEQ ID NO:2. The metes and bounds of the claim cannot be established. Claims 3, 5-8, 39-43, 45-52, 66 and 67 are rejected for same reason because they depend on claim 2.

Regarding claim 42, the recitation of “a polypeptide sequence at least encoded by a polynucleotide sequence at least...” renders the claim indefinite because it is unclear what is intended by the term “at least encoded by” in the context of the claim. Clarification is required. Claim 43 is rejected for same reason because it depends on claim 42.

Regarding claim 49, the recitation of “in said call” renders the claim indefinite there is no antecedent basis for such “call.” It would be remedial to amend the claim to recite “in said cell.”

### ***Response to Arguments***

In response to the written description rejection, Applicants assert that the instant amendment requires a polypeptide encoded by a polynucleotide at least 98% homologous to a polynucleotide encoding amino acids 1-168 or SEQ ID NO:2, and additionally clarifies that the method is for modulating activation of NFkB signaling pathway that includes contacting a cell having TRADE activity with a TRADE $\alpha$  polypeptide in an amount sufficient to modulate the activation of NFkB signaling pathway associated with TRADE activity in the cell.

This amendment is not sufficient to overcome the instant rejection for same reasons as set forth in the previous office action, and for lack of description as asserted above. Moreover, the instant claims are directed to a method of modulating the NFkB signaling pathway using “a

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polypeptide comprising at least 98% homology to 1-168 of SEQ ID NO:2.” According to the instant specification, the “TRADE” activity is much attributed to the C-terminal portion and the IC domain of the TRADE $\alpha$  and TRADE $\beta$  molecule, not the extracellular domain encoded by 1-168 of SEQ ID NO:2 (see page 133, last paragraph). As such, the specification fails to describe the instant invention in a way to convey one skilled in the art that the inventor had possession of the invention at the time the application was filed.

In response to the enablement rejection, Applicants assert that the instant amendment would obviate this rejection.

The argument is not persuasive. The claimed invention lack enablement for same reason as set forth in the previous office actions. In addition, the instant claims are amended to recite a method is for modulating activation of NFkB signaling pathway that includes contacting a cell having TRADE activity with a TRADE $\alpha$  polypeptide in an amount sufficient to modulate the activation of NFkB signaling pathway associated with TRADE activity in the cell. As discussed above, the instant specification does not teach, or give a working example that any polypeptide comprising the extracellular domain of TRADE $\alpha$  that have 98% homology with SEQ ID NO:2 modulates the NFkB signaling pathway in a cell genetically modified to have TRADE activity or naturally having TRADE activity. According to the disclosure of the instant specification, the activation of NFkB signaling by TRADE polypeptide resides in the intracellular domain, and there is no evidence that the extracellular domain can modulate this activity. Therefore, whether the extracellular domain can modulate the activation of NFkB signaling in a cell having TRADE activity is unpredictable, and whether any polypeptide comprising a sequence having 98% homology with 1-168 of SEQ ID NO:2 can modulate the activation of NFkB signaling in a cell

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having TRADE activity is also unpredictable. As such, the claimed invention is not enabled by the instant specification.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

